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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/215,163	12/18/98	STINSON J	04995.0032-0

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FINNEGAN HENDERSON FARABOW
GARRETT & DUNNER
1300 I STREET NW
WASHINGTON DC 20005-3315

EXAMINER	
RYAN, V	
ART UNIT	**PAPER NUMBER**
1641	17

DATE MAILED: 06/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/215,163	Stinson et al
Examiner	**Group Art Unit**
V. Ryan	1641

☒ Responsive to communication(s) filed on *Mar 14, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-31* is/are pending in the application.

Of the above, claim(s) *3-12, 21, 22, 24-28, 30, and 31* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, 13-20, 23, and 29* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3 and 5*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group I (drawn to the humanized monoclonal antibody), Species B (drawn to the monoclonal antibody that binds to shiga toxin type 2) in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out any supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, it is noted that claim 26, which was included in the election for the monoclonal antibody that binds to shiga toxin type (i.e., Species B), is directed the monoclonal antibody that binds to shiga toxin type 1. Therefore, the restriction is hereby modified: Claim 26 in now in Species A and will not be examined with the elected invention and species. Since claim 2 is directed to both types of monoclonal antibodies, it will be examined as a generic claim.

In this application:

Claims 1-31 are pending.

Claims 3-12, 21, 22, 24-28, 30 and 31 are withdrawn from consideration by the examiner as being drawn to a nonelected invention.

Claims 1, 2, 13-20, 23 and 29 are now under examination.

Please Note: Misnumbered claims 16, 15 and 16-30 have been renumbered as claims 15-31, respectively, in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. (See page 2 of the February 14, 2000 Office Action.)

Drawings

The drawings are objected to under 37 CFR 1.84 or 1.152 for the reasons stated on PTO 948. Correction is required.

Claim Rejections - 35 USC § 112

Claims 1, 13-20, 23 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of the monoclonal antibodies. Because it is not clear that the monoclonal antibodies possessing the properties of the monoclonal antibodies are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification requires the use of the monoclonal antibodies, a suitable deposit for

patent purposes is required. Accordingly, filing of evidence of the reproducible production of the monoclonal antibodies, one of ordinary skill in the art could be assured to the ability to practice the invention as claimed. Pages 11 and 19 indicate the monoclonal antibodies have been deposited at the American Type Culutre Collection (ATCC). However, the specification does not fully comply with the deposit of biological materials requirement.

If the deposit has been made under the provisions of the Budapest Treaty, an affidavit or declaration filed by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of the deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, and that all restrictions will be irrevocably removed upon the granting of a patent on this application is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) The deposits will be maintained in a public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longer; and

(d) The deposits will be replaced if they should become non-viable or non-replicable.

In addition, a deposit of the biological material that is capable of self-replication either directly or indirectly must be viable at the time of the deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;

2) The name and address of the depositor;

3) The date of deposit;

4) The identity of the deposit and the accession number given by the depository;

5) The date of the viability test;

6) The procedures used to obtain a sample if the test is not done by the depository; and

7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the monoclonal antibodies described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claim Rejections

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more

than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 13-20, 23 and 29 are rejected under 35 U.S.C. 103 as being obvious by any one of Speirs et al or O'Brien et al in view of Shitara et al.

Speirs et al (Can. J. Microbiol. 37:650-653, 1991) teach the 11E10 monoclonal antibody which binds to shiga-toxin II. (See especially Abstract; page 651, first column).

O'Brien et al (US Patent #5,747,272) also teach the 11E10 monoclonal antibody of the IgG1 subclass with a kappa light chain. (See especially column 4, lines 38-58).

Speirs et al or O'Brien et al, however, do not teach humanized monoclonal antibodies.

Shitara et al (US Patent #5,866,692) teach a method of producing humanized chimera antibodies. Humanized chimera does not cause formation of anti-mouse immunoglobulin antibody in the body of the patient and therefore side effects and reduced. (See especially Abstract; column 1, lines 10-48).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to synthesize and express the humanized chimera antibody which binds to the shiga-like toxin type II. One having ordinary skill in the art would have been motivated to do this to avoid the side effect caused by anti-mouse immunoglobulin antibody when monoclonal antibody is administered, yet still achieve an effective therapeutic effect.

The Group and/or Art Unit location of your application in the Patent and Trademark Office may have changed. To aid in correlating any papers for this application, all further

correspondence regarding this application should be directed to Group Art Unit 1641.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703)305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1641 is (703)308-4242.

V. Ryan
Patent Examiner/Art Unit 1641
May 2000
Ryan/vr

James C. Housel 6/5/00
JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER